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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,384	11/14/2000	Murthy V. Simhambhatla	25141-0590	3452

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EXAMINER

RAGONESE, ANDREA M

ART UNIT	PAPER NUMBER
3749	10

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/713,384	SIMHAMBHATLA ET AL.
	Examiner	Art Unit
	Andrea M. Ragonese	3749

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 1-8, 17-20, 22 and 23 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 9-16 and 21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 28, 2003 have been fully considered but they are not persuasive. The 102(e) and 103(a) rejections of **claims 10-16 and 21**, as described in the previous Office Action, Paper No. 8, are hereby repeated and have been made **FINAL**.

- In response to applicant's argument regarding **claim 9** that no suggestion is made in the reference that a compliant polymer is to be blended and crosslinked with a multifunctional agent, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).
- In response to applicant's argument regarding **claims 10-15** that no expandable balloon having stiffening zones is mentioned in the secondary reference, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined

teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

- In response to applicant's argument regarding **claim 21** that neither the structure of a balloon nor the coating of zones thereon is described, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in-
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. **Claim 9** is rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al. (US 2002/0103455). Regarding **claim 9**, Zhang et al. discloses a balloon catheter

comprising a soft polymer blended and crosslinked with a multifunctional agent, so that the balloon exhibits compliant radial expansion to a desired working diameter within a first pressure range, and substantially less expansion about the first pressure range (paragraphs [0044]-[0045]).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 10 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2002/0103455 A1) in view of Gilson et al. (US 2002/0062133 A1).**
Zhang et al. teaches a balloon catheter apparatus comprising all limitations recited in **claims 10 and 15-16**, with the exception of longitudinally extending stiffening zones circumferentially disposed on at least a section of the balloon. Gilson et al. teaches the use of a tubular body **72**, as shown in Figure 29, comprising longitudinally extending stiffening zones **76** symmetrically spaced and circumferentially disposed on at least a section of the tubular body **72** for expanding with adjacent portions of tubular body **72** such that the tubular body **72** section expands to a substantially cylindrical configuration (paragraph [0228]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize stiffening zones in the balloon catheter of Zhang et al. because, as taught by Gilson et al., it is well-known in the art to utilize

stiffening ribs in a tubular body in order to control axial growth of the balloon during inflation (paragraph [0233]).

6. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2002/0103455 A1) in view of Gilson et al. (US 2002/0062133 A1) and further in view of Engelson et al. (US 5,312,356). Zhang et al. in view of Gilson et al. teaches a balloon catheter apparatus comprising all limitations recited in **claim 11**, with the exception of longitudinally extending stiffening zones comprised of a polymeric material coextruded as an intermittent first layer on the outer most edge of the expanded balloon. Engelson et al. teaches the use of coextruding a surface coating of a polymeric material as an intermittent first layer on the outer most edge of a tubular body (column 11, lines 15-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a polymeric surface coating in the balloon catheter of Zhang et al. in view of Gilson et al. because, as taught by Engelson et al., it is well-known in the art to utilize polymeric material coatings on a tubular body in order to control physical characteristics, such as axial growth of the balloon during inflation (column 3, lines 50-57).

7. **Claims 12 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2002/0103455 A1) in view of Gilson et al. (US 2002/0062133 A1) and further in view of Samson et al. (US 6,090,099). Zhang et al. in view of Gilson et al. teaches a balloon catheter apparatus comprising all limitations recited in **claims 12 and 21**, with the exception of longitudinally extending stiffening zones comprised of a cross-linked polymeric material. Samson et al. teaches the use of a coating of a cross-linked

polymeric material as longitudinally extending stiffening zones (column 6, lines 23-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a cross-linked polymeric material surface coating in the balloon catheter of Zhang et al. in view of Gilson et al. because, as taught by Samson et al., it is well-known in the art to utilize cross-linked polymeric material coatings on a catheter in order to control physical characteristics, such as axial growth of the balloon during inflation, by increasing strength and allowing heat shrinking (column 6, lines 30-31).

8. **Claims 13-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2002/0103455 A1) in view of Chen et al. (US 5,565,523). Zhang et al. teaches a balloon catheter apparatus comprising all limitations recited in **claims 13-14**, with the exception of at least one specific polymer with glass transition temperature of about 20° C to about 60° C selected from the group consisting of polyamide-ether block copolymer, polyether-ester block copolymer, polyester-ester block copolymer, polyester-urethane block copolymer, polyether-urethane block copolymer, polycarbonate-urethane block copolymer, polyolefin, and polyolefin block copolymer. Chen et al. teaches the use of at least one of these polymers for use in making medical devices including catheters and balloons for dilatation catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the specific polymers as the material used to make the balloon catheter of Weber et al. because, as taught by Chen et al., it is well-known in the art to utilize these such polymers since they exhibit a relatively low flexural or tensile modulus, a relatively high

tensile strength and a relatively high elongation to break—material characteristics that are generally desirable in medical devices—in order to provide for controlled axial or radial expansion (column 4, lines 19-54).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is (703) 306-4055. The examiner can normally be reached on Monday through Friday from 7 am until 4 pm ET.
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on (703) 308-1935. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

amr
May 27, 2003



M. S. Lazarus
Supervisory Patent Examiner
Group 3700